

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/004626

International filing date (day/month/year)
02.11.2004

Priority date (day/month/year)
03.11.2003

International Patent Classification (IPC) or both national classification and IPC
A61M15/08, B05B11/00, B65D83/14

Applicant
GLAXO GROUP LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

10/577977
International application No.
PCT/GB2004/004626

10/577977 03 MAY 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II Priority

1. ☐ The following document has not been furnished:

- ☐ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. ☒ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
4. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and Industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 55

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 55
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

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International application No.
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-54
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-54
Industrial applicability (IA)	Yes: Claims	1-54
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2004/004626

IAP20 RECEIVED 03 MAY 2006

Re Item V.

1 The following documents are referred to in this communication:

D1 : FR-A-2 812 726 (2002-02-15)

D2 : EP-A-0 412 524 (1991-02-13)

D3: WO-A-2004/080606 (2004-09-23)

2 **INDEPENDENT CLAIM 1**

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 does not involve an inventive step in the sense of Article 33(3)PCT.

a) Document **D1**, which is considered to represent the most relevant state of the art to the subject matter of claim 1, discloses (the references in parentheses applying to this document) a fluid dispensing device ("dispositif de pulvérisation de produit fluide" shown in Fig.2) for spraying a fluid into a body cavity, the device comprising:

- a housing ("corps 100"),
- a nozzle ("tête de distribution nasale") for insertion into a body cavity,
- a fluid discharge device ("réservoir 10", "pompe 20") moveably housed within the housing, the fluid discharge device having a longitudinal axis and comprising a container ("réservoir 10") containing a fluid medicament formulation ("produit fluide") to be dispensed and a compression pump ("pompe 20") having a suction inlet located within the container (cf. Fig.2) and a discharge tube extending along the longitudinal axis for transferring fluid from the pump to the nozzle,
- finger operable means ("système d'actionnement 50") moveable with respect to the longitudinal axis of the fluid discharge device to apply force to the container to move the container along the longitudinal axis towards the nozzle so as to actuate the compression pump, and
- wherein a pre-load means ("élément de précompression 52") is provided to prevent actuation of the compression pump until a pre-determined force ("seuil de précompression") is applied to the finger operable means.

The subject-matter of independent claim 1 differs from the disclosure of D1 in that said

fluid medicament formulation has a viscosity of from 10 to 2000 mPa.s at 25°C.

- b) The problem of producing a well-defined spray may be significant where the medicament formulation is in the form of a relatively viscous formulation. If the actuator is moved in a slow or unpredictable manner a strong and well-defined spray may not be produced and so the medicament formulation may not be effectively dispensed. The problem to be solved by the present invention may therefore be regarded as "how to provide a fluid dispensing device producing a strong and well-defined spray for spraying relatively viscous formulation".
- c) In view of **D2** the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons: The document **D2** provides a nozzle adapter which makes it possible to spray viscous medical solutions having a viscosity of 500 to 3000 mPa.s. The skilled person would therefore regard it as a normal option to include the configuration of the spray nozzle adapter of **D2** in the fluid dispenser described in document **D1** in order to provide a fluid dispensing device producing a strong and well-defined spray for spraying relatively viscous formulation.
- d) Therefore the features disclosed in **D1** and **D2** would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (Article 33(3) PCT).

3 INDEPENDENT CLAIM 54

The same reasoning applies, *mutatis mutandis*, to the subject-matter of the corresponding independent claim 54, which therefore is also considered not inventive (Article 33(3) PCT).

4 DEPENDENT CLAIMS 2-53

Dependent claims 2-53 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT) since the additional features of these claims

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- are **EITHER** already known from D1,
- **OR** represent slight constructional changes and/or normal mechanical designs which come within the scope of the customary practice followed by persons skilled in the art. Consequently, the subject-matter of claims 2-53 also lacks an inventive step (Article 33(3) PCT).

- 5 The subject-matter of claims 1-54 is considered industrially applicable (Article 33(4) PCT) since it can be made or used in any kind of industry.

Re Item VI.

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO-A-2004/080606 (D3)	23.09.2004	11.03.2004	

Re Item VII.

- 6 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents **D1** and **D2** is not mentioned in the description, nor are these documents identified therein.
- 7 The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT with those features known in combination from the prior art (document **D1**) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 8 The features of the claims are not provided with reference signs placed in parentheses

(Rule 6.2(b) PCT).

Re Item VIII.

- 9 The vague and imprecise statement in the description on page 78 (lines 12-15) implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them.
- 10 The dependency of claim 17 (cf. "A fluid dispensing device as claimed ??? in which the pre-load means ...") is not clearly defined (Article 6 PCT). For the purpose of this written opinion, claim 17 has been considered as depending on any of claims 1 to 7 since it relates to the pre-load means.